510(k) Summary

DEC 2 7 2012

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name and Address of Applicant

Spine View, Inc.
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B. Contact Person

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C. Date Prepared

November 30, 2012

D. Device Name

Trade Name:	FlexLite™ Camera
Common Name:	Arthroscope
Classification Name:	Arthroscope

E. Device Classification

Classification:	21 CFR §888.1100
Product Code:	HRX
Device Class:	Class II

F. Predicate Device

Spine View, Inc. submits that the subject FlexLite™ Camera is substantially equivalent to the predicates, Vision-Sciences ENT-5000 flexible endoscope (K102733, K072073) and the Spine View SpineVu MiniScope (K081051).

G. Device Description

The Spine View FlexLite™ Camera is a flexible, reusable arthroscope designed for endoscopic visualization during diagnostic or interventional spinal procedures with access to the target area established through a surgical opening. The device includes fiber-optic illumination bundles with an integrated LED light source in the handle and a distal tip CCD image sensor with associated electronics. The camera is offered to support NTSC and PAL video formats. The FlexLite™ Camera is designed for use with the commercially available Vision-Sciences DPU-5050 Video Processor Unit (K102733, K072073) for image display and transfer. The FlexLite™ Camera contains neither software nor firmware. The FlexLite™ Camera is provided non-sterile to the customer and must be cleaned and sterilized by the user prior to each use.

H. Intended Use

The FlexLite™ Camera is indicated for use for endoscopic visualization in the surgical area of the cervical, thoracic, or lumbar spine during diagnostic or interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.

I. Technological Comparison

The Spine View FlexLite™ Camera has similar features as compared to the predicate devices as shown in the tables below:

Manufacturer Model Name 510(k) Number	**Spine View, Inc. FlexLite™ Camera TBD**	**Vision-Sciences, Inc. ENT-5000 Surgical Videoscope K102733, K072073**	**Spine View, Inc. SpinVu Miniscope K081051**
Classification	21CFR888.1100 HRX, Class II	21CFR888.1100 & 21CFR874.4760 HRX& EOB, Class II	21CFR888.1100 HRX, Class II
Indications for Use	The FlexLite™ Camera is indicated for use for endoscopic visualization in the surgical area of the cervical, thoracic, or lumbar spine during diagnostic or interventional spinal procedures such as discectomy, nucleotomy	The ENT-5000 is intended for use in flexible endoscopic examination of the upper airway, vocal cords and/or nasal passages; and for use diagnostic arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through	The SpineVu Endoscopic Spine System (SESS) and SpinVu MiniScope are indicated for use for endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine and are accessorized with

Manufacturer Model Name 510(k) Number	Spine View, Inc. FlexLite™ Camera TBD	Vision-Sciences, Inc. ENT-5000 Surgical Videoscope K102733, K072073	Spine View, Inc. SpinVu Miniscope K081051
	and foraminotomy.	either a natural or surgical openings.	surgical and coagulation tools for interventional spinal procedures such as discectomy, nucleotomy and foraminatomy
Design	A reusable, flexible, video endoscope with no channel; for use with the Vision-Sciences Digital Video Processor with integrated LCD monitor.	A reusable, flexible, video endoscope with no channel; optional single-use, sterile, disposable sheath (various models and channel sizes); for use with the Vision-Sciences Digital Video Processor with integrated LCD monitor.	A reusable, flexible, video endoscope with no channel; with eyepiece on proximal end having port for illumination cable.
Diameter	2 mm	3.4 mm	0.8 mm
Working Length	1163 mm	320 mm	~11 inches (280mm)
Single Use?	Reusable (STERRAD®)	Reusable (EtO or Glutaraldehyde) (optional single-use sterile sheath)	Reusable (STERIS®)

The technological characteristics and principals of operation of the FlexLite™ Camera are substantially equivalent to the named predicate devices.

J. Non-Clinical Performance Data

The following non-clinical testing was conducted to support a determination of substantial equivalence to the predicate device.

• Dimensional Testing	• Biocompatibility Testing
• Performance Testing	• Design Validation Testing
• Durability Testing	• Cleaning Validation
• Environmental Testing	• Sterilization Validation
• Electrical Safety, Thermal Safety & EMC Testing	

The above testing confirmed that the FlexLite™ Camera performs according to the stated intended use. All data fell well within product specifications and external standard requirements. Results of non-clinical testing demonstrated that the Spine View FlexLite™ Camera is substantially equivalent to the predicate devices for its intended use.

K. Conclusions

The Spine View FlexLite™ Camera has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the FlexLite™ Camera functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter dated: December 27, 2012

Spine View, Incorporated
% Mbithi Muthini
Director, Quality and Regulatory
48810 Kato Road, Suite 100E
Fremont, California 94538

Re: K122134
Trade/Device Name: FlexLite™ Camera
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 30, 2012
Received: December 03, 2012

Dear Mbithi Muthini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122134

Device Name: FlexLite™ Camera

Indications for Use:

The FlexLite™ Camera is indicated for use for endoscopic visualization in the surgical area of the cervical, thoracic, or lumbar spine during diagnostic or interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.

Prescription Use ___X___ **Or** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off) for mkm
Division of Surgical Devices
510(k) Number K122134